



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,050	03/22/2004	James E. Kipp	IFT-6019	1570
MICHAEL MAYO, ESQ. BAXTER INTERNATIONAL INC. LAW DEPARTMENT ONE BAXTER PARKWAY, DF2-2E DEERFIELD, IL 60015				
EXAMINER				
KUGEL, TIMOTHY J				
ART UNIT		PAPER NUMBER		
1796				
MAIL DATE		DELIVERY MODE		
05/05/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/806,050

Applicant(s)

KIPP ET AL.

Examiner

Timothy J. Kugel

Art Unit

1796

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,9-14 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,9-14,16,17 and 22-25 is/are allowed.
- 6) ☒ Claim(s) 5-7,18-21 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-849)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1, 2, 5-7, 9-14, and 16-28 are pending as amended on 29 February 2008, claims 3, 4, 8 and 15 being cancelled.
2. The text of those sections of Title 35, US Code not included in this action can be found in a prior Office action.

Response to Amendment and Arguments

3. Applicant's argument, filed 29 February 2008, specifically that the limitation requiring the precipitation of organic compound to create the particles to occur outside of the chamber of the comminuting apparatus is supported by the original disclosure, has been fully considered and is persuasive.

The rejection of claims 1 and 9-14 under 35 USC 112, first paragraph, as failing to comply with the written description requirement has been withdrawn.

4. Applicants's other arguments, filed 29 February 2008, have been fully considered but are not persuasive.

Applicant argues that US Patent 5,314,506 (Midler hereinafter), fails to teach the limitations requiring the suspension to contact an impact surface or requiring the streams to avoid direct impingement and having the first and second streams be in substantially opposite directions; however it is the examiner's position that Midler, in figures 2 and 3 shows that the fluid streams would impact on the flat and/or semi-

spherical surfaces on both sides of the chamber and be re-directed in the substantially opposite direction as they enter the chamber and that the streams do not need to be directly impinging, which would meet the language of the instant claims.

Claim Rejections - 35 USC § 102

5. Claims 5, 7, 18-21 and 26-28 stand rejected under 35 USC 102(b) as being anticipated by Midler.

Midler teaches a method of producing a particle suspension comprising impinging jets of a solution of an organic compound in an organic solvent and an anti-solvent—including water—such that a high purity stable dispersion results (Column 2 Lines 16-19, Column 4 Line 55 – Column 5 Line 19 and Figures 2 and 3). Midler also teaches that the fluids of the process can contain a surfactant (Column 5 Lines 32-45) and that the fluids can be cooled with an ice bath (Example 2 Column 8 Line 55 – Column 9 Line 16). Midler shows that the fluid streams would impact on the flat and/or semi-spherical surfaces on both sides of the chamber and be re-directed in the substantially opposite direction as they enter the chamber (Figures 2 and 3). Further, Midler shows that the streams do not need to be directly impinging (Figure 2).

Claim Rejections - 35 USC § 103

6. Claim 6 stands rejected under 35 USC § 103(a) as being unpatentable over Midler as applied to claims 5, 7, 18-21 and 26-28 above in view of US Patent 3,685,261 (McIlvaine).

As detailed above, Midler teaches a method of producing a particle suspension comprising impinging jets of a solution of an organic compound in an organic solvent and an anti-solvent—including water—such that a high purity stable dispersion results. Midler also teaches that the fluids of the process can contain a surfactant and that the fluids can be cooled with an ice bath. Midler shows that the fluid streams would impact on the flat and/or semi-spherical surfaces on both sides of the chamber and be re-directed in the substantially opposite direction as they enter the chamber. Further, Midler shows that the streams do not need to be directly impinging.

Midler does not disclose expressly the use of the Venturi effect to combine the two fluid streams.

McIlvaine discloses a method and apparatus for dispersing two fluids including a Venturi (Column 1 Line 56 – Column 2 Line 15 and Figures 1-6).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use the Venturi of the apparatus of McIlvaine in the method of Midler. The rationale to do so would have been the teaching of McIlvaine that doing so would thoroughly mix and disperse the two fluids (McIlvaine Column 2 Lines 13-15).

Allowable Subject Matter

7. Claims 1, 2, 9-14 and 22-24 are allowed.

Claims 2 and 22-24 are allowed for the reason of record.

The following is an examiner's statement of reasons for allowance regarding claims 1 and 9-14: Midler, the closest prior art, fails to teach or fairly suggest the

precipitation of the organic compound to form the particles taking place outside the chamber of the comminuting apparatus.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Kugel whose telephone number is (571) 272-1460. The examiner can normally be reached 6:00 AM – 4:30 PM Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Timothy J. Kugel/
Patent Examiner, AU 1796